Initial REMS Approved: 7/2009
Most Recent Modification: 9/2011

Risk Evaluation and Mitigation Strategy

NDA 22-307

Trade Name: EFFIENT (prasugrel)

NDA 22-307 EFFIENT® (prasugrel)
Thienopyridine platelet inhibitor

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. Goal:

To mitigate the serious risk of bleeding associated with the use of EFFIENT by:

1. Informing patients of the serious risks associated with EFFIENT, particularly the increased risk of bleeding.

2. Communicating to prescribers about the increased risk of bleeding associated with EFFIENT and the need for appropriate patient selection.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be available for distribution with each EFFIENT prescription in accordance with 21 CFR 208.24.

B. Communication Plan

Lilly will implement a communication plan to healthcare providers including in particular interventional cardiologists, clinical cardiologists, emergency medicine physicians, internal medicine physicians, and primary care physicians that will convey the following information:

- The serious risk of bleeding associated with EFFIENT.
- Appropriate patient selection (emphasizing patients in whom EFFIENT should not be used).

The communication plan includes a Dear Healthcare Provider Letter and a Prescriber Brochure. This element of the REMS is not intended to continue over the lifetime of the product; it will function only to inform prescribers of the serious risk of bleeding associated with EFFIENT therapy for a period of 2 years.

1. Introductory Letter

Lilly will issue a Dear Healthcare Provider Letter to targeted healthcare providers within 45 days of approval. The purpose of this letter is to inform healthcare providers of the serious risk of bleeding associated with EFFIENT and the importance of appropriate use and proper patient selection.

2. Prescriber Brochure

The prescriber brochure will emphasize the key safety messages related to risk of bleeding and its management, including risk management by providing guidance on proper patient selection. In addition, the prescriber brochure provides healthcare providers with information to discuss with their patients. Lilly will disseminate the prescriber brochure after the completion of the initial presentation to the prescribers of the product during the first two years after launch.

C. Timetable for Submission of Assessments

The timetable for submission of assessment of the REMS is as follows:

Lilly will submit REMS assessments to the FDA at a minimum, by 18 months, by 3 years, and in the 7th year from the date of the initial approval of the REMS (July 10, 2009). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will conclude no earlier than 60 days before the submission date for that assessment. Eli Lilly will submit each assessment so that it will be received by the FDA on or before the due date.

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/s/

MARY R SOUTHWORTH
09/26/2011